REMARKS

Status of the Claims.

Claims 1, 3-4, 7-8, 10-12, 14-18, 21-24, 26-28, 30-36, 44-48, 62-66, 74-79, 93-94, 106-108, and 110-119 are pending with entry of this amendment. Claim 105 has been canceled without prejudice to subsequent renewal, including in a divisional or continuation application. New claims 120 and 121 have been added. Claims 1, 3, 7, 8, 10-12, 14-18, 21-24, 26-28, 30-36, 44-48, 62-66, 74-79, 93-94, 105-108, and 111-119 were rejected. Claims 4 and 110 have been substantively allowed. Applicants thank the Examiner for substantive allowance of these claims.

Claims 1, 3, 8, 10, 21-24, 26-28, 30-36, 65-66, 106, 108, 113, 117-119 are amended herein without prejudice to subsequent renewal of any subject matter canceled from any claim herein. All of the amendments to the pending claims introduce no new matter and are fully supported by the specification as filed. Applicants reserve the right to pursue and/or renew subject matter canceled from any claim herein without prejudice, including in a divisional or continuation application.

New claims 120 and 121 have been added. New claim 120 specifies an isolated or recombinant polynucleotide comprising a polynucleotide sequence having at least 99% sequence identity to the entire length of the polynucleotide sequence of SEQ ID NO:8 or the complementary sequence thereof, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked.

New claim 121 specifies an isolated or recombinant polynucleotide comprising a polynucleotide sequence having at least 99.5% sequence identity to the polynucleotide sequence of SEQ ID NO:8 or the complementary sequence thereof, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked.

Claims 120 and 121 are fully supported by the application as filed and do not include any new matter.

Rejections Under 35 USC § 112, first paragraph.

Claims 3, 8, 14-18, and 105 were rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner takes the position that these claims encompass a large genus of polynucleotide sequences that must

retain the recited structural identity to SSEQ ID NO:8 as well as retaining the recited functional activity relative to that of the reference CMV promoters. Office Action, p. 4. The Examiner finds that the skilled artisan would not have been able to envision a sufficient number of specific embodiments embraced by the claims to describe the broadly claimed genus of nucleic acids having the recited functional activity and thus the skilled artisan would reasonably have concluded applicants were not in possession of the claimed invention. The rejection of claim 105 has been mooted by cancellation of that claim. The rejection of claims 3, 8, and 14-18 is respectfully traversed as follows.

For the reasons presented below, Applicants respectfully submit that the claimed genus of nucleic acids does not have substantial variability, the exemplified species are indeed representative of the claimed genus, and therefore one of skill would conclude that Applicants were in possession of the claimed genus.

The claimed genus does not have substantial variation for at least the following reasons. All of the claimed molecules must possess the following characteristics: they must have the specified sequence (e.g., 98% or 99% sequence identity to the entire length of the polynucleotide sequence of SEQ ID NO:8) and they must possess the specified functional activity.

The Examiner Training Materials, which are entitled "Synopsis of Application of Written Description Guidelines" (hereinafter "Training Materials", which were referenced in column 1 of page 1101 of the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement, published in the Federal Register, Vol. 66, No. 4 January 5, 2001 pp. 1099-1111 (hereinafter "Written Description Guidelines"), expressly confirm that Applicants' claims satisfy the Written Description requirement. Example 14 on pages 53-55 of the Training Materials provides a fact scenario in which the specification claims a "protein having SEQ ID NO:3 and variants thereof that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction A → B", and provides an actual reduction to practice of a single disclosed species. In the analysis it is concluded that a genus of proteins having at least 95% identity to the reference sequence and exhibiting the specified catalytic activity was considered "not [to] have substantial variation". In particular, the Training Materials state in Example 14:

> There is actual reduction to practice of the single disclosed species. The specification indicates that the genus of proteins that must be variants of SEQ ID NO: 3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to

> the reference sequence, SEQ ID NO: 3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant for identifying all of the at least 95% identical variants of SEQ ID NO:3 which are capable of the specified catalytic activity. One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by members of the genus. (*Training Materials, paragraph bridging pages 54-55*).

As noted above, the claimed genus nucleic acids defined by claims 3, 8, and 14-18 exhibits the following relevant identifying characteristics: each member of the genus must possess the specified promoter activity, and each member of the genus must have the specified sequence identity to the entire length of the polynucleotide sequence of SEQ ID NO:8, and, which, as noted above, is less variation than that of the genus described in Example 14 of the Training Materials, which was determined to "not have substantial variation".

Furthermore, the specification clearly provides assays for detecting the ability of the claimed nucleic acids to function as promoters to express a polypeptide-encoding sequence that is operably linked thereto. Additionally, procedures for making nucleic acids which have 98% or 99% identity to SEQ ID NO:8 by, e.g., nucleotide substitutions, are routine in the art and assays is described in the specification which will identify those nucleic acids having the claimed functional activity.

Moreover, there is actual reduction to practice of the species SEQ ID NO:8, which promotes expression of a polypeptide-encoding nucleic acid to which SEQ ID NO:8 sequence is operably linked at a level that is equal to or greater than the level of expression of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to the human CMV promoter polynucleotide sequence -- SEQ ID NO:19 or SEQ ID NO:20.

The species is representative of the claimed genus because it possesses all of the relevant identifying characteristics of the genus, namely: (a) all members of the genus have at least 998% or 99% sequence identity to the reference sequence SEQ ID NO:8; and (b) all members of the genus can be identified by way of the functional assay which Applicants have provided (i.e., to determine promoter activity). Furthermore, as explained above, the claimed genus does not have substantial variation.

In light of the above, one of skill in the art would conclude from the specification that Applicants were in possession of the necessary common attributes possessed by the members of the

genus claimed in presently pending claims 3, 8, and 14-18. Therefore, the specification meets the requirements of 35 USC § 112 paragraph 1 as providing adequate written description for the claimed invention. Applicants therefore respectfully request the rejection of these claims under 35 USC § 112 paragraph 1 be withdrawn.

Rejections Under 35 USC § 112, second paragraph.

Claims 3, 10, 21-24, 26, 28, 30-36, 44-48, 62-66, 74-79, 93-94, 105, and 111 were rejected under 35 USC § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter with Applicant regards as his invention.

Specifically, claims 3 and 111 were rejected as vague and indefinite due to inadvertent incorrect dependencies. This rejection has been overcome by amending claim 3 to be dependent upon claim 1 and amended claim 111 to be dependent on claim 108. Withdrawal of the rejection is respectfully requested.

In addition, claims 10, 21-24, 26-28, and 30-36 were rejected as vague and indefinite due to the phrase "corresponding to about." The Examiner also suggested that "SEQ ID NO:21" be specified, since this is the consensus sequence shown in Figures 8A-8I. This rejection has been overcome by amending claims 10, 21-24, 26-28 and 30-36 to delete the term "about" in the recited phrase and substituting the term "SEQ ID NO:21" for "Figures 8A-8I." Withdrawal of the rejection is respectfully requested.

The rejection of claim 105 has been mooted by cancellation of that claim.

Rejections Under 35 USC § 102.

1. Chapman

Claims 1, 3, 12, 14-18, 24, 26-28, 35-36, 44-48, 62-66, 74-78, 105, and 107 were rejected under 35 USC § 102(b) as allegedly being anticipated by Chapman et al. (Nucleic Acids Research 19(14):3979-3986 (1991)) [hereinafter "Chapman"]. The Examiner finds that Chapman discloses a hCMV sequence that has only 95.8% sequence identity over the entire length of the polynucleotide sequence of SEQ ID NO:8, but discloses an arbitrary subsequence that has a local similarity to SEQ ID NO:8 of 98.8% over residues 335-2099 of the 2.4 kb sequence of hCMV. The Examiner maintains the previous arguments made of record. The Examiner also takes the position that the phrase "about equal to" in the limitation "at a level that is about equal to or greater than" in

specific claims is not explicitly defined in the specification and that one of ordinary skill in the art would necessarily expect that the Chapman sequence would at least retrain some promoter activity that would be sufficient to meet the "broad limitation of being 'at a level of about equal to' that of the reference promoters." Office Action, p. 9.

The Examiner also takes the position that the sequence disclosed by Chapman comprises deletions, such as at residue 321 of SEQ ID NO:8, and that the term "corresponding to about" as applied to residues of the consensus sequence is not explicitly defined in the specification, such that the term can be interpreted to read broadly on any number of residues. Office Action, p. 10.

The rejection of claim 105 has been mooted by cancellation of that claim. With regard to the remaining rejected claims, Applicants continue to traverse this rejection for at least the reasons stated in the Amendment filed on December 1, 2003. Chapman does not teach the isolated or recombinant nucleic acid as particularly defined by independent claim 1. Moreover, Chapman does not teach each of the additional specific limitations included in any of dependent claims 3, 12, 14-18, 24, 26-28, 35-36, 44-48, 62-66, 74-78, and 107. However, in an effort to expedite prosecution of the instant application, Applicants have amended independent claim 1 to specify more particularly an isolated or recombinant nucleic acid comprising a polynucleotide sequence that has at least 98% sequence identity to the entire length of the polynucleotide sequence of SEQ ID NO:8 or the complementary polynucleotide sequence thereof, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked. Furthermore, claims 3, and 8 have been amended to delete the term "about" in the phrase "at a level that is about equal to or greater than" that the Examiner has argued. In addition, claims 24, 27-28, and 35-36, the term "about" in the phrase "corresponding to about" as indicated above.

With this amendment, Applicants believe the rejection of independent claim 1 and claims 3, 12, 14-18, 24, 26-28, 35-36, 44-48, 62-66, 74-78, and 107 dependent thereon has been overcome. Chapman does not disclose an isolated or recombinant nucleic acid comprising a polynucleotide sequence that has at least 98% sequence identity to the entire length of the polynucleotide sequence of SEQ ID NO:8 or the complementary polynucleotide sequence thereof, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked. Nor does Chapman disclose the nucleic

acids, vectors, or methods defined by any of dependent claims 3, 12, 14-18, 24, 26-28, 35-36, 44-48, 62-66, 74-78, and 107 – particularly as presently amended. For at least these reasons, Applicants respectfully submit that the rejection has been overcome. Withdrawal of the rejection is respectfully requested.

2. Haynes

Claims 1, 3, 7-8, 12, 14-18, 44-48, 62-66, 74-79, 93-94, 106-108, and 111-119 were rejected under 35 USC § 102(b) as allegedly being anticipated by Haynes (US 6,200,959) [hereinafter "Haynes"]. The Examiner states that Haynes discloses an expression vector (pWRG7077) comprising an HCMV IE promoter linked to a multiple cloning site for insertion of antigen coding sequences (SEQ ID NO:7). The Examiner finds that the promoter sequence from pWRG7077 disclosed by Haynes has 99.1% sequence across nucleotides 123-1765 of SEQ ID NO:8.

Although Applicants respectfully traverse this rejection, in an effort to expedite prosecution, Applicants have amended claims 1, 106, 108, 113, and 117 to specify more particularly sequence identity to the entire length of the polynucleotide sequence of SEQ ID NO:8. Haynes does not disclose any sequence that has 98% sequence identity over the entire length of the polynucleotide sequence of SEQ ID NO:8, as explicitly defined by claims 1 and 106. Nor does Haynes does not disclose any sequence that has 99% sequence identity over the entire length of the polynucleotide sequence of SEQ ID NO:8, as explicitly defined by claims 108, 113, and 117. For at least these reasons, Applicants respectfully submit that the rejection has been overcome. Withdrawal of the rejection is respectfully requested.

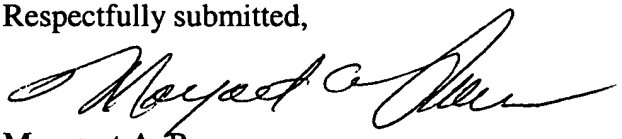
Rejections Under 35 USC § 101.

Claims 65-66 and 118-119 were rejected under 35 USC § 101 because the claimed invention was allegedly directed to non-statutory subject matter. This rejection has been overcome by amending these claims to specify an "isolated or recombinant" cell. Withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application in any way, the Examiner is invited to telephone the undersigned at (650) 298-5809.

Respectfully submitted,



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